# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF OREGON

FRIENDS OF ANIMALS,

Plaintiff,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and ANDREW WHEELER, in his official capacity as Acting Administrator of the U.S. Environmental Protection Agency,

Defendants,

and

THE HUMANE SOCIETY OF THE UNITED STATES

Defendant-Intervenor.

Case No. 2:17-cv-1410-SI

OPINION AND ORDER

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## Michael H. Simon, District Judge.

Plaintiff, Friends of Animals, seeks judicial review of the EPA's denial of its request to initiate a Special Review of a pesticide registered with the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). After hearing from the parties on cross-motions for summary judgment, United States Magistrate Judge Patricia Sullivan issued her Findings and Recommendation ("F&R"). Judge Sullivan concluded that the EPA's decision not to initiate a Special Review was not subject to judicial review and dismissed the case for want of jurisdiction. After *de novo* review<sup>1</sup>, the Court rejects the F&R and concludes that the Court does have jurisdiction over Plaintiff's case. The Court remands the case to Judge Sullivan for a recommendation on the merits of the cross-motions for summary judgment.

#### **BACKGROUND**

### A. FIFRA

FIFRA sets out detailed procedures governing the sale, use, and distribution of pesticides and requires that all pesticides must be registered with the EPA. 7 U.S.C. § 136a(a). Before a pesticide can be properly registered with the EPA, the Administrator must determine that the pesticide does "not generally cause unreasonable adverse effects on the environment."

Id. § 136(a)(c)(5)(D). FIFRA defines an "unreasonable adverse effect on the environment" as

<sup>&</sup>lt;sup>1</sup> Under the Federal Magistrates Act, a district court may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate." 28 U.S.C. § 636(b)(1). If a party files objections to a magistrate's findings and recommendations, "the court shall make a *de novo* determination of those portions of the report or specified proposed findings or recommendations to which objection is made." *Id.*; *see also* Fed. R. Civ. P. 72(b)(3).

one that poses "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).

After a pesticide is registered with the EPA, FIFRA provides certain review procedures for the EPA to continually reevaluate a pesticide's risks and benefits. If the EPA finds that a registered pesticide, "when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment," the EPA may institute proceedings either to "cancel its registration or change its classification," or to "determine whether or not its registration should be cancelled or its classification changed." *See* 7 U.S.C. § 136d(b)(1)-(2). The EPA also has the authority to suspend the registration of the pesticide immediately "[i]f the [EPA] determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings." 7 U.S.C. § 136d(c)(1).

The EPA may conduct a public interim administrative review, called a Special Review, see 40 C.F.R. § 154.1(a); 50 Fed. Reg. 12200, to determine whether a pesticide should be cancelled or reclassified, see 7 U.S.C. § 136d(b). "[A] decision to initiate a Special Review must be 'based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risks to man or to the environment." 50 Fed. Reg. 49006 (quoting 7 U.S.C. § 136a(c)(8)). The regulations promulgated under FIFRA identify six criteria for the EPA Administrator to consider in determining whether "based on a validated test or other significant evidence . . . the use of the pesticide" poses unreasonable risks to humans and the environment such that the EPA should initiate a Special Review. 40 C.F.R. § 154.7(a) (identifying six criteria for EPA Administrator to consider). If the Administrator finds that at

least one of those six criteria is met, she "shall consider available evidence concerning both the adverse effect of the pesticide and the magnitude and scope of exposure to humans and nontarget organisms." *Id.* § 154.7(b). The EPA may initiate Special Review of a pesticide either on its own initiative or "at the suggestion of any interested party" who submits a "petition[] to begin the Special Review process." *See id.* § 154.10.

Any final orders of the Administrator made specifically under 7 U.S.C. § 136d are subject to judicial review under 7 U.S.C. § 136n(a). *See* 7 U.S.C. § 136d(h). District courts have jurisdiction to review "the refusal of the [EPA] to cancel or suspend a registration or change a classification not following a hearing and other final actions of the [EPA] not committed to the discretion of the [EPA] by law." *See id.* § 136n(a). Appellate courts have jurisdiction to review the validity of orders made after a public hearing. *Id.* § 136n(b).

#### B. ZonaStat-H

At issue in this case is the continued registration under FIFRA of the pesticide ZonaStat-H, a contraceptive for wild horses and burros that contains the active ingredient porcine zona pellucida ("PZP"). PZP is a naturally-occurring animal glycoprotein harvested from the ovaries of pigs. EPA000044. The pesticide ZonaStat-H is made up of PZP and two adjuvants² which, when combined and injected into mares, blocks the attachment of sperm to egg, thereby preventing fertilization. *Id.*; EPA000038. ZonaStat-H is used to manage wild horse and burro populations.

In 2009, The Humane Society of the United States ("HSUS") submitted an application to register ZonaStat-H under FIFRA for the specific use of limiting populations of wild and feral horses and burros. HSUS submitted information in support of its application for registration,

<sup>&</sup>lt;sup>2</sup> An adjuvant is a substance that enhances the body's immune response to an antigen.

including published journal articles and peer-reviewed studies on the use of PZP. EPA granted HSUS's waiver of the requirements to submit subchronic, developmental, reproductive, genotoxicity, neurtoxicity, and immunotoxicity studies based on "the lack of toxicity to the target animal; history of safe use of the vaccine; the mode of action and fate of the product's metabolites; the limited opportunity of exposure to non-target animals, applicators, and the public; and the lack of immunotoxicity as shown in the published literature." *Id.* The EPA also granted HSUS exemptions from all testing requirements ordinarily required for terrestrial, non-food pesticide application. EPA000107; EPA000037. On January 30, 2012, the EPA issued Registration No. 86833-1 for ZonaStat-H to HSUS pursuant to section 3(c)(5) or FIFRA. EPA000021.

On May 19, 2015, Plaintiff submitted a Petition to the EPA requesting that the agency conduct a Special Review to consider new scientific evidence demonstrating the need to cancel the registration of the pesticide ZonaStat-H for population control of wild horses and burros. EPA000001-20. The Petition also requested that the EPA "[i]ssue an order suspending Registration [of ZonaStat-H] pursuant to 7 U.S.C. § 136d(c)(1) during the Special Review" and "[h]old a hearing pursuant to 7 U.S.C. § 136d(b)(2) to determine if [the registration for ZonaStat-H] should be canceled or reclassified." EPA000003. Plaintiff contends that its Petition presents new evidence demonstrating that the use of ZonaStat-H to control wild horse and burro populations causes significant harm to nontarget organisms, including foals and untreated members of the herd, and that these risks are not outweighed by the benefits of the pesticide. Plaintiff also submitted evidence consisting of new scientific studies published after HSUS submitted its registration application in 2009 and after the EPA approved the registration in 2012. Plaintiff argues that this new evidence demonstrates that ZonaStat-H poses unreasonable

adverse effects on the target animals, nontarget animals, and the interrelationships amongst the target and nontarget animals, and that these effects cannot be offset by the benefits of the pesticide.

On December 15, 2016, the EPA issued a letter denying Plaintiff's Petition for Special Review. First, the EPA stated that "[t]he criterial for initiating Special Review are set out in 40 C.F.R. [§] 154.7." EPA000033. The EPA then proceeded to analyze each of Plaintiff's contentions about the harms of ZonaStat-H and PZP under the criteria outlined in the regulation. EPA000033-35.The EPA concluded that initiating a Special Review was not warranted. *Id.* The EPA decided not to issue a notice of intent to cancel or reclassify and declined to issue a suspension order. *Id.* Finally, the EPA declined to exercise its discretion to hold a hearing to determine whether or not the registration of ZonaStat-H should be cancelled or reclassified. *Id.* 

#### **DISCUSSION**

FIFRA confines judicial review by federal district courts to the "EPA's refusal to cancel or suspend a registration not following a hearing, its refusal to change a classification, and any "other final actions." Beyond Pesticides/Nat'l Coal. Against the Misuse of Pesticides v. Whitman, 294 F. Supp. 2d 1, 7 (D.D.C. 2003) (quoting 7 U.S.C. § 136n(h)) (emphasis in original). No party disputes that there is anything non-final about the EPA's decision not to initiate a Special Review. The parties disagree, however, on whether a denial of a petition for Special Review is a reviewable action rather than one confined exclusively to agency discretion.

The Administrative Procedure Act ("APA") provides that agency action is not subject to judicial review when the "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). Section 706(2)(A) of the APA, however, instructs courts to review agency action to determine if the agency action was "arbitrary, capricious," or otherwise constituted an "abuse of discretion." 5 U.S.C. § 706(2)(A). There is some tension between these two statutory PAGE 6 – OPINION AND ORDER

admonitions, and courts have thus construed § 701(a)(2) to block reviewability only when the agency enjoys some sort of special discretion. 33 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 8325. The Supreme Court has interpreted § 701(a)(2) to apply only where the agency discretion is so broad and unfettered that there is, in essence, "no law to apply." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (internal citation omitted).

Courts apply a "strong presumption' favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). This presumption is rebuttable, however, and "[i]t fails when a statute's language or structure demonstrates that Congress wanted an agency to police its own conduct." *Id.* Rebutting this presumption is no easy task, and the agency "bears a 'heavy burden' in attempting to show that Congress 'prohibit[ed] all judicial review' of the agency's compliance with a legislative mandate." *Id.* (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)).

Congress provided for judicial review of all "other final actions" of the EPA under FIFRA, evincing a clear intent on the part of Congress for the EPA's final actions, even actions other than those specified in § 136(d), to be subject to judicial review. 7 U.S.C. § 136n(a). Thus, Defendant faces a steep burden to rebut the presumption of reviewability.

Additionally, the Court notes that EPA construed Plaintiff's Petition, in addition to a petition for Special Review, as a petition "pursuant to section 6(c)(1) of [FIFRA], 7 U.S.C. § 136d(c)(1) to issue an order to suspend this registration during the special review and/or proceeding to cancel or reclassify" or "pursuant to section 6(b)(2) of FIFRA, 7 U.S.C. § 136d(b)(2), to hold a hearing to determine if this registration should be cancelled or

reclassified." EPA000032. The EPA denied both of these requests. Thus, the EPA refused "to cancel or suspend a registration or to change a classification" under § 136d of FIFRA and such orders "are judicially reviewable by the district courts of the United States." 7 U.S.C. § 136n(a); 136d(h). Plaintiff seeks review specifically, however, of the EPA's denial of its Petition to initiate a Special Review proceeding.

"FIFRA . . . provides that a decision to initiate a Special Review must be 'based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risks to man or to the environment." 50 Fed. Reg. 49006 (quoting 7 U.S.C. § 136a(c)(8)). The regulation governing the "Criteria for initiation of Special Review" identifies six specific criteria the EPA Administrator may consider when determining whether to initiate a Special Review, and if the EPA determines that "a pesticide use satisfies one of the criteria for issuance of a Special Review . . . the Administrator *shall* consider available evidence concerning both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide." 40 C.F.R. § 154.7(b) (emphasis added). "These criteria assure that the determination of whether or not a pesticide poses an unreasonable risk will be based both on the toxic effects associated with the pesticide and the actual or projected exposure of humans and other nontarget organisms to the pesticide." 50 Fed. Reg. 49004.

Courts have concluded that there is "law to apply" even when the statutory text requires the agency to make a judgment call. In *Citizens to Preserve Overton Park*, the Supreme Court found that the statute contained adequate "law to apply" to facilitate judicial review even though the statute required the agency "to engage in a wide-ranging balancing of competing interests" in determining whether a proposed route for a highway was "feasible" or "prudent." 401 U.S. at 411. The Court expressly rejected the argument that because the ultimate decision rests with

the agency and is based on its subjective analysis of the statutory concerns, that decision is insulated from all judicial review. *Id.* at 413. Similarly, a statute that required the EEOC to engage in a conciliation process with employers accused of sexual harassment yet provided absolutely no standards guiding what the conciliation process would entail did not divest courts of the power to review whether the EEOC had adequately engaged in conciliation. *Mach Mining*, 135 S. Ct. at 1652. By providing "no standards by which to judge' the EEOC's performance of its statutory duty, the government argued that "Congress deprived courts of any 'judicially manageable criteria' with which to review the EEOC's efforts." *Id.* (quoting *Heckler v. Chaney*, 470 U.S. 821, 830 (1985)). The Supreme Court disagreed and concluded although that Congress provided the EEOC "with wide latitude," which was relevant in determining the scope of judicial review, Congress had clearly removed from the EEOC's discretion the decision whether to engage in any conciliation at all. Therefore, Congress supplied a "perfectly serviceable standard for judicial review: Without any 'endeavor' at all, the EEOC would have failed to satisfy a necessary condition of litigation." *Id.* 

Although the decision whether to initiate a Special Review is ultimately up to the judgment of the Administrator, Congress has not left the Administrator without guidance as to what factors should inform that decision. By requiring that a Special Review be based on a "validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment," 7 U.S.C. § 136a(c)(8), Congress did not intend that the risks posed by a registered pesticide to humans and the environment were to be ignored. *See, e.g.*, *Citizens to Preserve Overton Park*, 401 U.S. at 412. The EPA, when publishing the regulations governing Special Review in the Federal Register, examined the legislative history of FIFRA and concluded that "[t]he legislative history of section 3(c)(8) makes it clear that Congress wanted

the EPA to have some solid evidence of risk to humans or the environment in hand before initiating the lengthy and time-consuming" Special Review process. 50 Fed. Reg. 12190.

The statutory text supplies the Court with a "law to apply" that is sufficient to determine whether the agency may have abused its discretion by, for example, refusing to take into account any risks posed by a registered pesticide. Just as in *Mach Mining*, one course of action, here the failure to consider the risks of a pesticide based on validated tests, has been taken off the table by Congress. If the EPA enacted a policy of denying all petitions for Special Review filed on a Tuesday, without any consideration of the risks to humans and the environment, a court would easily be able to determine that the EPA's decision was arbitrary, capricious, and an abuse of discretion. The regulations, specifically 7 C.F.R. § 154.7, provide further "law to apply" when evaluating whether the EPA's refusal to initiate a Special Review was an abuse of discretion, and the EPA actually evaluated Plaintiff's petition under those regulatory criteria. *See* EPA000033-35 (analyzing petition under 40 C.F.R. § 154.7 criteria). These "set forth the substantive standards for initiating a Special Review of a pesticide." 40 C.F.R. § 154.1(b).

The EPA argues that the criteria outlined in the statute and the regulations apply only in instances when the agency decides *to* initiate a Special Review and that there are no guidelines whatsoever that apply to a decision *not* to initiate a Special Review.<sup>3</sup> This argument is illogical. Any petition for Special Review requires the agency to make decision between two options: to initiate a Special Review or not to initiate a Special Review. Choosing the first option implicitly rejects the second and vice versa. Thus, a decision to not initiate a Special Review must involve an analysis of the factors to be considered in deciding whether to initiate a Special Review and a

<sup>&</sup>lt;sup>3</sup> The EPA concedes that a decision to initiate a Special Review is subject to judicial review because the statutory and regulatory text spells out clear criteria for the court to use in evaluating whether the agency's decision constituted an abuse of discretion in 40 C.F.R. § 154.7.

determination that those factors are not met. In other words, the criteria that the agency uses when determining to initiate a Special are the same criteria that the agency uses when determining not to initiate a Special Review.

The text of the Special Review regulations demonstrate that the criteria outlined in 40 C.F.R. § 154.7 are considered by the Administrator in evaluating a petition Special Review regardless of whether the Administrator ultimately decides to initiate a Special Review. For example, § 154.10 states that "[t]he administrator may evaluate a pesticide under the criteria of § 154.7 either on his own initiative, or at the suggestion of any interested person." The regulation contemplates that the § 154.7 factors are instrumental in considering any petition regarding a pesticide—regardless of whether that petition is ultimately granted or denied. Similarly, when the EPA published the final regulations in the federal register, it noted that the criteria listed in § 154.7 were instrumental to "the determination of whether *or not* a pesticide poses an unreasonable risk." 50 Fed. Reg. 49004 (emphasis added). The criteria outlined by the statute and the regulations thus apply to the agency's decision-making process, regardless of whether the agency ultimately decides to grant or deny a petition for Special Review.

Neither the law nor the regulation, however, *require* the EPA Administrator to initiate a Special Review. *See* 7 U.S.C. § 136a(c)(8) ("the Administrator may not initiate a public interim administrative review process . . . unless such interim administrative process is based on a validated test or other significant evidence"); 40 C.F.R. § 154.7(a) ("The Administrator may conduct a Special Review of a pesticide use if he determines, based on a validated test or other significant evidence . . . ."). But the use of the statutory term "may" does not, by itself, preclude judicial review. *See Envtl. Def. Fund, Inc. v. Ruckelshaus*, 439 F.2d 584, 590 (D.C. Cir. 1971) (citing *Mulloy v. United States*, 398 U.S. 410, 416-418 (1970)). The use of the word "may" in

FIFRA has never been found to vest such discretion in the agency as to preclude all judicial review. *See id.* at 593.

To the extent that a denial of a petition for Special Review is tantamount to a denial of a motion to reopen or reconsider the initial registration, judicial review is not precluded because the petition was based on new evidence not available at the time of the initial registration. See EPA000002. I.C.C. v. Brotherhood of Locomotive Engineers recognized that when an agency "refuses to reopen a proceeding, what is reviewable is merely the lawfulness of the refusal." Absent some provision of law requiring a reopening (which is not asserted to exist here), the basis for challenge must be that the refusal to reopen was 'arbitrary, capricious, [or] an abuse of discretion." 482 U.S. 270, 278 (1987). Further, the Supreme Court recognized that "all of [its] cases entertaining review of a refusal to reopen appear to have involved petitions alleging 'new evidence' or 'changed circumstances" as opposed to merely alleging that an initial decision was made in error. Id. Thus, I.C.C. supports the proposition that when an agency denies a petition to reopen or reconsider based on new evidence or changed circumstances, the denial of the petition may be subject to review for an abuse of discretion. Because Plaintiff contends that its Petition involved new scientific studies on the use of ZonaStat-H in wild horses and burros, the agency's denial of that Petition is subject to judicial review to determine if the Administrator's decision was "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C § 706(2)(A).

Other courts have assumed that judicial review is available for the denial of a petition for Special Review. The Ninth Circuit, in *Merrell v. Thomas*, noted that FIFRA "provides for judicial review of important EPA decisions" and that the Special Review process could have been an available remedy to an appellant who sought to challenge the registrations of seven

pesticides used near his wife's farm. 807 F.2d 776, 782 (9th Cir. 1986). Similarly, the Eighth Circuit, when rejecting appellant's attempt to use the Bird Acts to challenge the EPA's decision to register a pesticide under FIFRA, noted that appellants "could petition the EPA to cancel registrations or request other action. If the EPA refused, [appellants] could obtain judicial review in the district court as provided by FIFRA." *Defenders of Wildlife v. Administrator, E.P.A.*, 882 F.2d 1294, 1302 (8th Cir. 1989). Indeed, in Defenders of Wildlife, it was the EPA that argued that "Defenders' remedy lies in petitioning the EPA to cancel the three challenged registrations. *See, e.g.*, 40 C.F.R. § 154.10 (1987) (petitioning to initiate Special Review). If the EPA refuses to cancel, Defenders may seek judicial review in the district court under an arbitrary and capricious standard. *See* 7 U.S.C. § 136n(a)." *Id.* at 1298.

Although the Ninth Circuit has not addressed this issue directly, other district courts have reviewed an agency's decision not to initiate a Special Review. In *Ellis v. Housenger*, the plaintiffs requested that the EPA suspend a pesticide's registration or, alternatively, "promptly initiate Special Review and cancellation procedures for [the pesticide] pursuant to 7 U.S.C. § 136d and then suspend its registration pending completion of the cancellation procedures based on the ongoing and imminent harm posed." 252 F. Supp. 3d 800, 807 (N.D. Cal. 2017). The court found that it had jurisdiction to review the EPA's denial of the petition and that the standard of review set forth in the APA applied. *Id.* at 808. In a subsequent opinion, the court concluded that "a party may petition the EPA to cancel or suspend a pesticide registration where,

<sup>&</sup>lt;sup>4</sup> The EPA actually argued in *Merrell v. Thomas* that a petition for Special Review was an administrative remedy available to the plaintiff that must be exhausted prior to seeking judicial review. The EPA argued that Section 16(a) of FIFRA provided that an agency's denial of a petition is reviewable in district courts, and noted the availability of the Special Review process as a form of petition available to the public. *See* Appellee's Brief at 25-27 & n.10. The Ninth Circuit agreed with this assessment of the petition and Special Review process as forms of administrative remedies that must be exhausted before filing suit in federal court. *Merrell*, 807 F.2d at 782 & n.3.

as here, the party asserts that the pesticide 'causes unreasonable adverse effects on the environment,' *see* 7 U.S.C. § 136d; *see also* 40 C.F.R. §§ 154.1(a), 154.10, and, if unsuccessful, may seek review in the federal courts, *see* 7 U.S.C. § 136d(h)." *Ellis v. Bradbury*, 2014 WL 1569271, at \*6 (N.D. Cal. 2014) (citing Special Review regulations).

Plaintiff's Petition contains nearly identical wording to the petition reviewed by the Court in *Ellis*. Here, as in *Ellis*, the EPA denied Plaintiff's Petition for a Special Review, denied its request for a hearing, and refused to cancel or suspend the registration of the pesticide under section 136d of FIFRA. *See* EPA000032 (construing Plaintiff's requests as "pursuant to section 6(c)(1) of [FIFRA]" and "pursuant to section 6(b)(2) of FIFRA").

FIFRA and its accompanying regulations provide clear guidance on what the Administrator should consider when determining whether or not to initiate a Special Review and FIFIRA specifically authorizes judicial review of unspecified "other final actions." *See* 136n(a); 136a(c)(8); 40 C.F.R. § 154.7. Defendant is unable to rebut the "strong presumption favoring judicial review of administrative action." *Mach Mining*, 135 S. Ct. at 1653. There is no indication in the text of FIFRA that Congress intended the Special Review process to be peculiarly insulated from judicial review or that the Administrator enjoys some special discretion in deciding not to initiate a Special Review that she does not enjoy in deciding to initiate a Special Review. The statute and regulations show that Congress intended that the decision whether to initiate a Special Review be "based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risks to man or to the environment." 7 U.S.C. § 136a(c)(8). This provides courts with sufficient law to apply when analyzing whether the agency's decision was arbitrary, capricious, or an abuse of discretion. As such, like "other final

actions" of the EPA under FIFRA, the agency's refusal to initiate Special Review is subject to judicial review under the standard of review provided by the APA. 5 U.S.C. § 706.

# **CONCLUSION**

The Court declines to adopt the Findings and Recommendation (ECF 60). The case is remanded to Judge Sullivan for a determination on the merits of the parties' cross-motions for summary judgment.

## IT IS SO ORDERED.

DATED this 23rd day of April, 2019.

/s/ Michael H. Simon
Michael H. Simon
United States District Judge